

REMARKS

After entry of this amendment, claims 1, 3-7, 39, and 44-47 are pending. Applicants respectfully request entry of the above claim amendments as they are believed to put the claims in condition for allowance or, alternatively, in better form for consideration on appeal. Thus, entry under 37 CFR §1.116 is correct.

Claims 8-32, 34-38, and 40-43 are cancelled without prejudice or disclaimer as being directed to non-elected subject matter. Applicants preserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications. New claim 47 has been added and finds support *inter alia* in the original claim 2. Further support is found in the specification at page 14, lines 36-40 and page 18, lines 18-23. The claims have been amended without prejudice or disclaimer to address the various points made in the Official Action. Support is found *inter alia* in the original claims. Claim 1 finds further support in the specification at page 11, lines 10-12, page 14, lines 36-40, and page 18, lines 18-23. No new matter has been added.

Rejection Under 35 U.S.C. § 112

Indefiniteness Rejection

Claims 1, 3-7, 39, and 44-46 were rejected under 35 USC §112, second paragraph, as being indefinite. The Examiner alleges that the term “stringency” is relative with no definite meaning. Applicants respectfully disagree. However, to expedite prosecution, claims have been amended without prejudice or disclaimer to further define the “high stringency condition” by reciting particular hybridization conditions. In view of the present amendment, reconsideration and withdrawal of the rejection is respectfully requested.

Written Description Rejection

Claims 1, 3-7, 39, and 44-46 stand rejected under 35 USC §112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants respectfully traverse. However, to expedite prosecution, claims have been amended without prejudice or disclaimer to recite the percent identity as 90%. Applicants respectfully submit that claims as amended overcome this rejection.

The Examiner alleges that the specification fails to describe a representative number of species within the claimed genus or sufficient structural correlation to function. Applicants

respectfully disagree. While Applicants disagree that no structure/function relationship is disclosed, or known in the art, as alleged by the Examiner, the claims are patentable since, pursuant to the revised written description guidelines, the scope of the subject matter being claimed satisfies the written description requirement.

Initially, the claimed subject matter relates to a method for generating or increasing the resistance against the phylum Oomyceta by expressing a transgenic Rpi-blb2 protein encoding nucleic acid molecule in a plant. As set forth in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991), the test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had possession of the claimed subject matter at the time of filing. According to the “Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, ‘Written Description’ Requirement,” at page A-6, 3rd column of the “Written Description Training Materials” (“Guidelines,” March 25, 2008 revision), possession of an invention can be shown “in a variety of ways, including description of an actual reduction to practice.” The present application describes an actual reduction to practice of the claimed method in Example 12. Thus, possession of the claimed method is shown, and the rejection should be withdrawn.

Additionally, even viewing the nucleic acid as an “element” of the method claim, it is respectfully submitted that the written description requirement is satisfied as to that element in view of the revised Guidelines. As exemplified in Example 11A of the Guidelines, a claim reciting a nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to a specific sequence was found adequately described with only one single species disclosed in the specification, where an art-recognized structure-function relationship is not present. According to the Example 11A, the disclosure of the single sequence combined with the pre-existing knowledge in the art regarding the genetic code and its redundancies would have put one in possession of the genus of nucleic acids that encode the polypeptide with at least 85% sequence identity with the specified sequence. Additionally, with the aid of a computer, one skilled in the art could have identified all of the nucleic acids that encode a polypeptide with at least 85% sequence identity with the specified sequence.

As amended, claim 1 now requires that the nucleic acid molecule used in the claimed method is one encoding a polypeptide with at least 90% sequence identity with a polypeptide encoded by the nucleic acid sequence of SEQ ID NO: 3, 5, or 6, or the polypeptide of SEQ ID NO: 2 or 4, and is thus claiming a higher level of identity than that of Example 11A of the Guidelines.

With regard to the rejection based on the recitation of “high stringent condition for hybridization,” it is believed that the present claim amendment renders this issue moot by reciting specific hybridization conditions in part (d) of claim 1.

For all of the above reasons, one of ordinary skill in the art, when reading the present application, would clearly envision Applicants’ possession of the claimed method. Reconsideration and withdrawal of this rejection is respectfully requested.

Enablement Rejection

Claims 1, 3-7, 39, and 44-46 stand rejected under 35 USC §112, first paragraph, for allegedly lack of an enabling disclosure. The Examiner maintains the position that the specification does not provide guidance as to which amino acid residues may be modified, substituted, or deleted while maintaining the functional activity. Applicants respectfully disagree.

As discussed in the Amendment And Reply Under 37 CFR §1.111 dated October 24, 2007, the specification provides detailed description including working examples on how to make and use the claimed method. Furthermore, the specification discloses conserved regions of Rpi-blb2 (Figure 14), within which one skill in the art would know to avoid any substitutions or modification. In view of the detailed description, guidance, working examples, and high level of skill, the specification enables the full scope of the claim without undue experimentation. On these facts, an analysis under *In re Wands* supports enablement. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (routine screening of hybridomas was not “undue experimentation;” the involved experimentation can be considerable, so long as “routine”). Note that the test for whether experimentation is “undue” is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the

invention claimed. *Ex parte Jackson*, 217 USPQ 804, 807 (1982). The detailed guidance provided in the present specification, the skill and knowledge of the art, and the routine nature of the identification and isolation of additional genes for practicing the claimed method overcome the unpredictability alleged by the Examiner.

The above analysis is in consistent with the Board's decision in *Ex parte Kubin*, 83 USPQ2d 1410 (B.P.A.I. 2007)(hereinafter "*Kubin*"), where the Board held that a claim encompassing 80% amino acid sequence identity to the disclosed sequence was fully enabled. *Kubin* at 1416. As the Board noted in *Kubin*, even though practicing the full scope of the claims might have required extensive experimentation, the experimental techniques were well-known in the art, so the experimentation would have been routine and thus, not undue. *Id.* at 1416.

As in *Kubin*, the experimentation required to practice the present claims (making and screening mutant sequences and transgenic plants for practicing the claimed method) is routine in nature and clearly not "undue." Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner further rejects the claims alleging that the specification, while teaching transgenic expression to increase the activity of Rpi-blb2 protein, does not provide guidance as to other methods for increasing the activity of Rpi-blb2 protein. In response, claim 1 as amended now recites: "... increasing the activity of a Rpi-blb2 protein in the plant or a tissue, organ or cell of the plant or a part thereof by expressing a transgenic Rpi-blb2 protein encoding nucleic acid molecule" Accordingly, the rejection is believed to be rendered moot.

CONCLUSION


For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications.

Accompanying this response is a petition for a two-month extension of time to and including June 8, 2008 to respond to the Office Action mailed January 8, 2008 with the required fee. No further fee is believed due. However, if any additional fee is due, the Director is hereby

authorized to charge our Deposit Account No. 03-2775, under Order No. 13477-00002-US from which the undersigned is authorized to draw.

Respectfully submitted,

By 
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